

**PUBLIC HEALTH DEPARTMENT[641]**

**Adopted and Filed**

**Rule making related to radiation machines and radioactive materials**

The Department of Public Health hereby amends Chapter 37, “Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material,” Chapter 38, “General Provisions for Radiation Machines and Radioactive Materials,” Chapter 39, “Registration of Radiation Machine Facilities, Licensure of Radioactive Materials and Transportation of Radioactive Materials,” Chapter 40, “Standards for Protection Against Radiation,” Chapter 41, “Safety Requirements for the Use of Radiation Machines and Certain Uses of Radioactive Materials,” and Chapter 45, “Radiation Safety Requirements for Industrial Radiographic Operations,” Iowa Administrative Code.

*Legal Authority for Rule Making*

This rule making is adopted under the authority provided in Iowa Code section 136C.3.

*State or Federal Law Implemented*

This rule making implements, in whole or in part, Iowa Code section 136C.3.

*Purpose and Summary*

Items 1, 7, 10, 13, 15, 16 and 17 amend rules to reflect current federal regulations. Items 4, 8, and 9 amend rules to update citations and remove language regarding a fee that the Department has not charged and does not intend to charge. The remaining items amend rules to meet United States Nuclear Regulatory Commission (NRC) compatibility requirements pursuant to the stipulations of Iowa’s status as an NRC agreement state.

*Public Comment and Changes to Rule Making*

Notice of Intended Action for this rule making was published in the Iowa Administrative Bulletin on January 17, 2018, as **ARC 3578C**. The Department received comments from the NRC requesting the inclusion of an additional subrule in rule 641—39.5(136C) in order to meet NRC compatibility requirements. The NRC determined that if its suggestions were incorporated in the proposed regulations, they would meet the compatibility and health and safety categories established in the Office of Nuclear Material Safety and Safeguards (NMSS) Procedure SA-200, “Compatibility Categories and Health and Safety Identification for NRC Regulations and Other Program Elements.” The requested subrule is incorporated in a new Item 12 in this adopted rule making, and the Items that were published as 12 to 24 under Notice of Intended Action have been renumbered as 13 to 25. No other comments were received.

*Adoption of Rule Making*

This rule making was adopted by the State Board of Health on March 14, 2018.

*Fiscal Impact*

This rule making has no fiscal impact to the State of Iowa.

*Jobs Impact*

After analysis and review of this rule making, no impact on jobs has been found.

## *Waivers*

Any person who believes that the application of the discretionary provisions of this rule making would result in hardship or injustice to that person may petition the Department for a waiver of the discretionary provisions, if any, pursuant to the Department's variance and waiver provisions contained in 641—Chapter 178.

## *Review by Administrative Rules Review Committee*

The Administrative Rules Review Committee, a bipartisan legislative committee which oversees rule making by executive branch agencies, may, on its own motion or on written request by any individual or group, review this rule making at its [regular monthly meeting](#) or at a special meeting. The Committee's meetings are open to the public, and interested persons may be heard as provided in Iowa Code section 17A.8(6).

## *Effective Date*

This rule making will become effective on May 16, 2018.

The following rule-making actions are adopted:

ITEM 1. Amend subrule 37.1(4) as follows:

**37.1(4)** All references to any Code of Federal Regulations (CFR) in this chapter are those in effect as of ~~July 16, 2014~~ May 16, 2018.

ITEM 2. Amend paragraph **37.27(3)“a”** as follows:

a. For the purpose of complying with these rules, licensees shall use an appropriate method listed in 10 CFR 37.7 to submit to the U.S. Nuclear Regulatory Commission, Director, Division of Facilities and Security, 11545 Rockville Pike, ATTN: Criminal History Program/Mail Stop TWB-05 B32M, Rockville, Maryland 20852, one completed, legible standard fingerprint card (Form FD-258, ORIMDNRCOOOZ), electronic fingerprint scan or, where practicable, other fingerprint record for each individual requiring unescorted access to category 1 or category 2 quantities of radioactive material. Copies of these forms may be obtained by writing the Office of the Chief Information Services Officer, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, by calling 1-630-829-9565, or by e-mail to [FORMS.Resource@nrc.gov](mailto:FORMS.Resource@nrc.gov). Guidance on submitting electronic fingerprints can be found at <http://www.nrc.gov/site-help/e-submittals.html>.

ITEM 3. Amend paragraph **37.29(1)“j”** as follows:

j. Commercial vehicle drivers for road shipments of category 1 and category 2 quantities of radioactive material;

ITEM 4. Amend paragraph **37.41(1)“c”** as follows:

c. Any licensee that has not previously implemented the security orders or been subject to the provisions of these rules shall provide written notification to the agency as specified in rule ~~641—37.3(136C)~~ 641—37.7(136C) at least 90 days before aggregating radioactive material to a quantity that equals or exceeds the category 2 threshold.

ITEM 5. Amend subparagraph **37.77(1)“a”(1)** as follows:

(1) The notification must be made to the NRC and to the office of each appropriate governor or governor's designee. The contact information, including telephone and mailing addresses, of governors and governors' designees, is available on the NRC's ~~Web site~~ website at <http://nrc-stp.oeml.gov/special/designee.pdf> ~~scp.nrc.gov/special/designee.pdf~~. A list of the contact information is also available upon request from the Director, Division of Intergovernmental Liaison and Rulemaking, Office of Federal and State Materials and Environmental Management Programs, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001. Notifications to the NRC must be to the NRC's Director, Division of Security Policy, Office of Nuclear Security and Incident Response,

U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001. The notification to the NRC may be made by e-mail to RAMQC\_SHIPMENTS@nrc.gov or by fax to 1-301-816-5151.

ITEM 6. Adopt the following **new** paragraph **37.77(1)“f”**:

*f. Protection of information.* State officials, state employees, and other individuals, whether or not licensees of the commission or an agreement state, who receive schedule information of the kind specified in 37.77(1)“b” shall protect that information against unauthorized disclosure as specified in 37.43(4).

ITEM 7. Amend subrule 38.1(2) as follows:

**38.1(2)** All references to any Code of Federal Regulations (CFR) in this chapter are those in effect as of ~~November 5, 2014~~ May 16, 2018.

ITEM 8. Amend rule **641—38.2(136C)**, definition of “Decay-in-storage,” as follows:

“*Decay-in-storage*” means the holding of radioactive material having half-lives of less than ~~65~~ 120 days, except Cobalt-57, until it decays to background levels. Before disposal in ordinary trash, the material must have been held for a minimum of ten half-lives and its radioactivity is indistinguishable from background as indicated by a survey meter set on its most sensitive scale with no interposing shielding.

ITEM 9. Amend paragraph **38.8(8)“b”** as follows:

*b.* Radioactive materials. Out-of-state persons wishing to bring sources of radioactive material into Iowa for business purposes may be subject to a reciprocity fee depending on the type of activity to be performed and the type of radioactive materials license possessed (refer to 641—subrule 39.4(90)). If a reciprocity fee is applicable, it shall be assessed at the rate for reciprocity specified in the radioactive materials fee schedule available through the agency for each 365-day reciprocity period. ~~In addition, if the agency performs an inspection of the out-of-state person’s activities while in Iowa, the appropriate inspection fee as specified in the radioactive materials fee schedule will be assessed.~~

ITEM 10. Amend subrule 39.1(3) as follows:

**39.1(3)** All references to any Code of Federal Regulations (CFR) in this chapter are those in effect as of ~~July 16, 2014~~ May 16, 2018.

ITEM 11. Amend paragraph **39.4(52)“a”** as follows:

*a.* Each person who receives source or by-product material pursuant to a license issued pursuant to these rules shall keep records showing the receipt, transfer, and disposal of the source or by-product material as follows:

(1) The licensee shall retain each record of receipt of the source or by-product material as long as the material is possessed and for three years following transfer or ~~disposal~~ disposition of the source or by-product material.

(2) The licensee who transferred the material shall retain each record of transfer ~~for three years after each transfer unless a specific requirement in another part of these rules dictates otherwise~~ of the source or by-product material until the agency terminates each license that authorizes the activity that is subject to the record-keeping requirement.

(3) The licensee who disposed of the material shall retain each record of disposal of the source or by-product material until the agency terminates each license that authorizes disposal of the material.

ITEM 12. Amend rule 641—39.5(136C) as follows:

**641—39.5(136C) Transportation of radioactive material.**

**39.5(1)** All persons who transport radioactive material or deliver radioactive material to a carrier for transport must comply with the applicable provisions contained in 10 CFR Part 71 and 49 CFR Parts 170 through 189. The regulations in 10 CFR Part 71 apply to any licensee authorized by specific or general license to receive, possess, use, or transfer licensed material, if the licensee delivers that material to a carrier for transport, transports the material outside the site of usage, or transports that material on public highways. No provision of 10 CFR Part 71 authorizes possession of licensed material.

**39.5(2)** The provisions of 10 CFR Part 71 are subject to the following conditions.

*a.* Not adopted by reference are 10 CFR 71.11, 71.14(b), 71.19, 71.31, 71.33, 71.35, 71.37, 71.38, 71.39, 71.41, 71.43, 71.45, 71.51, 71.55, 71.59, 71.61, 71.63, 71.64, 71.65, 71.70, 71.71, 71.73, 71.74, 71.75, 71.77, 71.85(a)-(c), 71.91(b), 71.101(c)(2), 71.101(d), 71.101(e), 71.107, 71.109, 71.111, 71.113, 71.115, 71.117, 71.119, 71.121, 71.123, and 71.125.

*b.* Where the words “NRC”, “Commission”, “Nuclear Regulatory Commission”, “United States Nuclear Regulatory Commission” or “Administrator of the appropriate Regional Office” appear in 10 CFR Part 71, substitute the words “Iowa Department of Public Health” except when used in 10 CFR 71.5(b), 71.10, 71.17(c)(3), 71.17(e), 71.85(c), 71.88(a)(4), 71.93(c), 71.95, 71.97(c), 71.97(c)(3)(iii), and 71.97(f).

*c.* The terms “certificate of compliance” and “compliance holder or applicant” apply to the NRC as it is the sole authority for issuing a package certificate of compliance.

*d.* Iowa form “Notice to Employees” must be posted instead of NRC Form 3 that is specified in 10 CFR Part 71.

ITEM 13. Amend subrule 40.1(5) as follows:

**40.1(5)** All references to any Code of Federal Regulations (CFR) in this chapter are those in effect as of ~~November 5, 2014~~ May 16, 2018.

ITEM 14. Amend ~~641—~~**Chapter 40**, Appendix D, Section I, “Manifest,” third paragraph, as follows:

NRC Forms 540, 540A, 541, 541A, 542, and 542A, and the accompanying instructions, in hard copy, may be obtained by writing or calling the Office of the Chief Information ~~Services~~ Officer, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0111, telephone (301)415-5877 or by visiting the NRC’s ~~Web site~~ website at www.nrc.gov and selecting forms from the index found on the home page.

ITEM 15. Amend paragraph **41.1(1)“b”** as follows:

*b.* All references to any Code of Federal Regulations (CFR) in this chapter are those in effect as of ~~November 5, 2014~~ May 16, 2018.

ITEM 16. Amend paragraph **41.2(1)“b”** as follows:

*b.* All references to any Code of Federal Regulations (CFR) in this chapter are those in effect as of ~~November 5, 2014~~ May 16, 2018.

ITEM 17. Amend paragraph **45.1(1)“b”** as follows:

*b.* All references to any Code of Federal Regulations (CFR) in this chapter are those in effect as of ~~November 5, 2014~~ May 16, 2018.

ITEM 18. Amend subrule **45.1(2)**, definitions of “Radiographic exposure device” and “Storage container,” as follows:

“*Radiographic exposure device*” (also called a camera or a projector) means any instrument containing a sealed source fastened or contained therein, in which the sealed source or shielding thereof may be moved or otherwise changed from a shielded to unshielded position for purposes of making a radiographic exposure (~~e.g., camera~~), or any other X-ray industrial system whereby a permanent or semipermanent image is recorded on an image receptor by action of ionizing radiation.

“*Storage container*” means a ~~shielded device~~ container in which sealed sources are secured, ~~transported~~, and stored.

ITEM 19. Amend subrule 45.1(4) as follows:

**45.1(4)** *Receipt, transfer, and disposal of sources of radiation.* Each licensee and registrant shall maintain records showing the receipt, transfer, and disposal of sealed sources and devices using DU for shielding and machine-produced sources of radiation. These records shall include the date, the name of the individual making the record, the radionuclide, number of curies or mass (for DU), and the make, model, and serial number of each source of radiation and device, as appropriate. Records shall be maintained for three years after they are made.

ITEM 20. Amend subparagraph **45.1(10)“a”(1)** as follows:

(1) It has been documented on the appropriate agency form or equivalent that such individual has received copies of and has demonstrated an understanding of:

1. The subjects outlined in Appendix A, presented in a 40-hour course approved by the agency, another agreement state, or the U.S. Nuclear Regulatory Commission;

2. The rules contained in this chapter and the applicable sections of ~~641—Chapters~~ Chapter 38, the applicable U.S. Department of Transportation and NRC transportation regulations in 641—Chapter 39, and 641—Chapter 40;

3. The appropriate conditions of license(s) or certificate(s) of registration;

4. The licensee’s or registrant’s operating and emergency procedures;

5. And developed competence to use, under the personal supervision of the radiographer, the licensee’s or registrant’s radiographic exposure devices, sealed sources, associated equipment, and radiation survey instruments that the assistant will use;

6. And has demonstrated competence in the use of radiographic exposure devices, sources, survey instruments and associated equipment described in 45.1(10)“a”(1) by successful completion of a practical examination covering this material.

ITEM 21. Amend subparagraph **45.1(10)“d”(3)** as follows:

(3) The specific duties of the RSO include, but are not limited to, the following:

1. to 12. No change.

13. To ensure that annual refresher safety training has been provided for each radiographer and radiographer’s assistant at intervals not to exceed 12 months.

ITEM 22. Amend paragraph **45.1(10)“e”** as follows:

*e.* Training and testing records. Each licensee and registrant shall maintain, for agency inspection, training and testing records which demonstrate that the applicable requirements of 45.1(10)“a” and “b” are met. Records of training for all industrial radiographic personnel must include personnel certification documents and verification of certification status, copies of written tests, dates of oral and practical examinations, and names of individuals conducting and receiving the oral and practical examinations. Records of annual refresher training and semiannual inspection of job performance for all industrial radiographic personnel must list the topics discussed during the refresher safety training, the dates the annual refresher safety training was conducted, and names of the instructors and attendees. For inspections of job performance, the records must also include a list showing the items checked and any noncompliances observed by the RSO. Records shall be maintained until disposal is authorized by the agency. The agency shall not release records for disposal unless the records have been maintained at least three years.

ITEM 23. Amend subparagraph **45.3(3)“a”(1)** as follows:

(1) The licensee may not use a source changer or a container to store licensed material unless the source changer or the storage container has securely attached to it a durable, legible, and clearly visible label bearing the standard trefoil radiation caution symbol in conventional colors, i.e., magenta, purple or ~~black~~ black on a yellow background, having a minimum diameter of 25 mm, and the wording: “CAUTION RADIOACTIVE MATERIAL, NOTIFY CIVIL AUTHORITIES (or name of company);” or “DANGER RADIOACTIVE MATERIAL, NOTIFY CIVIL AUTHORITIES (or name of company).”

ITEM 24. Amend subparagraph **45.3(6)“a”(10)** as follows:

(10) The inspection, ~~and~~ maintenance, and operability checks of radiographic exposure devices, survey instruments, source changers, storage containers, and radiation machines;

ITEM 25. Rescind subparagraph **45.3(7)“c”(3)**.

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EDITOR’S NOTE: For replacement pages for IAC, see IAC Supplement 4/11/18.